

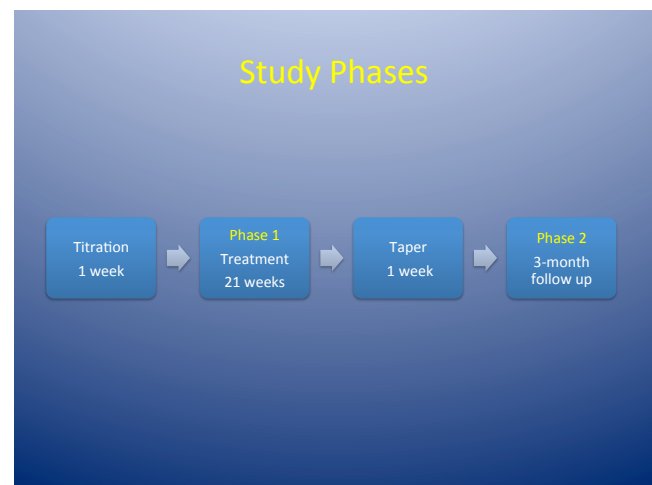
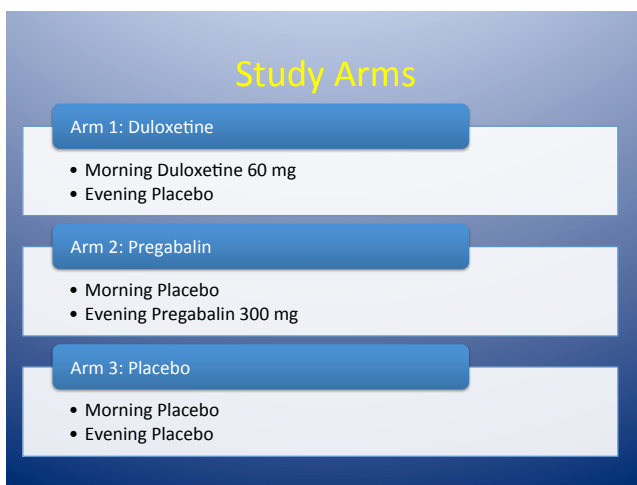
RESEARCH EXAMINING GULF WAR ILLNESS IN OUR NATIONS SERVICE-MEMBERS



At least 1 in 4 of the 700,000 U.S. Veterans who served in the 1990-1991 Gulf War suffer from Gulf War Illness. There are no known treatments.

Gulf War Illness refers to a complex of symptoms that typically include widespread chronic pain, persistent headache, memory and concentration problems, gastrointestinal difficulties, sleep disturbances and unexplained fatigue. These symptoms are similar to that of fibromyalgia, another multi-symptom condition. Although effective treatments for Gulf War Illness have yet to be found, progress has been made in identifying medications to treat fibromyalgia. REGIONS is a randomized controlled clinical trial that will test the efficacy of two FDA approved fibromyalgia medications for treating the symptoms Gulf War Illness.

Enrollment opened on June 2015. 180 Gulf War Veterans will receive 22 weeks of medication after randomization to: Group 1: duloxetine (Cymbalta ®) in the morning and placebo before bed; Group 2: placebo in the morning or pregabalin (Lyrica ®) before bed; or Group 3 placebo in the morning and placebo before bed.



Blood samples will be obtained on the first study visit to look for genes that may be associated with medication response and to develop a classification scheme to guide treatment choice in the future. Participants will come to the study site 14 times over 23 weeks. Telephone follow up will take place at week 34. Modest remuneration for time and travel is available. Most study visits will take about 2 hours, with a few lasting up to 4 hours, depending on the visit. The study ends in September 2019.

Gulf War Illness can be debilitating and disabling. Twenty-five years after the war, few Veterans have recovered or even substantially improved. Gulf War Illness presents a challenge to healthcare providers because there are few diagnostic tools and no approved treatment to care for these very ill Veterans. The Department of Veterans Affairs and the Department of Defense have given high priority to research that has the potential to identify safe and effective treatments that will provide significant improvement in the health and lives of these Veterans. REGIONS is one such study. REGIONS is funded by the VA's Office of Research and Development's Clinical Science and Research Development CX000795 and is registered with www.clinicaltrials.gov, SPLD-016-12F.



Study PI: Dena Davidson, Ph.D.
Research Director, VISN 17 Center of Excellence for Research on Returning War Veterans
Waco, Texas
For information call: Christine Kuhn, R.N.
(254) 297-3954